KENYA MEDICAL SUPPLIES AUTHORITY

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/WB-CERP/NCB 01/2021-2023 **Date: 13th September 2021**

ADDENDUM 2

To: All bidders,

REF: TENDER NO.: KEMSA/WB-CERP/NCB 01/2021-2023 PROCUREMENT OF MANUAL SARS-COV 2 RT-PCR DETECTION KITS (300,000 DETECTION TESTS)

You are hereby advised that the technical specifications have been amended and are herewith attached.

Yours faithfully,

Edward Buluma
For: Ag. Chief Executive Officer

SCHEDULE 1: Schedule of Requirements

Manual Sars-Cov 2 RT-PCR detection kits

1.3.1 Detailed Technical Specifications and Standards

SARS COV-2 manual detection kits
Detection technology and sensitivity

Specifications	Compliance to Technical Specifications (Yes/No)
1. The detection kit shall have at least Two (2) target genes that are specific for SARS-COV-2.	
2. Kits with any two genes that are specific for SARS-COV-2 are admissible. These genes include - N gene (either N1 or N2), ORF- (either 1a or 1b), P gene, RdRp, Replicase 1B. Please note that kits only containing a combination of subtypes N1 and N2 will be considered as having a single gene. Similarly, kits only containing a combination of subtypes ORF1a and ORF1b will be considered as having a single gene.	
3. If the kit has the E gene, it also shall have at least 2 other SARS-COV-2-specific genes excluding the S gene.	
4. If the kit has the S gene, it shall also have at least 2 other SARS-COV-2-specific genes excluding the E gene.	
5. Suppliers with kits based on sample release buffers for the extraction step shall only supply the detection kit.	
6. The detection kit must be truely multiplexed i.e., all SARS-COV-2-specific genes shall be detected in a single tube in a single reaction (one-step RT-PCR detection technology). For Example, if the kit has the N and the RdRp genes, both genes must be detected in the same reaction tube in a single PCR reaction. Kits that require step-wise testing for different genes in different PCR reactions are not suitable.	
7. The detection kit shall be compatible with SARS-COV-2-RNA extracted using extraction kits based on either magnetic bead and spin-column extraction technology.	
8. The detection kit shall have appropriate negative and positive controls.	
9. The kit shall also contain an endogenous or exogenous internal control or both.	

Specifications	Compliance to Technical Specifications (Yes/No)
10. Viral copy detection threshold sensitivity shall be as low as 5.0×10^2 copies/ml	
11. The detection kit shall be based on Fluorescent Probe Technology compatible with most real-Time PCR machines such as ABI 7500, and Bio-Rad as reference equipment.	
12. The kit shall be ready for use without the need for software upgrade of the RT-PCR machine.	
13. In order to ensure ease of allocation and distribution to different labs, the kits shall be packed in maximum packs of 100 tests.	
14. Diagnostic sensitivity shall be between 98% to 100% when using ABI 7500, and Bio-Rad as reference equipment.	
15. Each kit shall have an inlay card detailing the bench protocol and all accessory reagents and/or equipment supplied with the kit and those needed but not supplied together with the kit.	
Transport and storage conditions	
1. Cold chain requirement shall not be below -20°C (only requiring dry ice transport). Kits stable at higher temperature are also admissible.	
2. The detection kit shall have a shelf life of at least 6 months from the time of delivery.	
3. The kit shall be stable for up to 3 days at 4-8°C.	
Approvals	
1. The detection kit must be approved by either FDA and/or WHO or both or by other stringent regulatory authorities recognized by WHO.	
2. The detection kit must be registered locally by the Pharmacy and Poisons Board after meeting necessary validation steps.	
3. The detection kit must be in use in the source country (provide proof)	
Basis of evaluation	
1. An original manufacturer's full catalogue or section (in English) showing the requested specifications and the following parameters; product mark of quality, name of manufacturer, country of origin.	
2. These parameters must be highlighted with a bright marker on the catalogue	

Specifications	Compliance to Technical Specifications (Yes/No)
3. A signed and stamped check list indicating that the kit presented in the bid meets all the specifications requested for.	
4. An original inlay card detailing the laboratory protocol for use of the kit by laboratory personnel.	
5. A signed and stamped check list of equipment and reagents required for the extraction but not provided by the supplier.	

Company Name: _____

Signed: _____

Stamped: _____